REMARKS

A Notice of Allowance was mailed March 28, 2008. This Amendment is submitted with the issue fee payment to correctly state the relationship of the instant application to parent application 09/910,780, *e.g.*, to clarify that this application is a continuation application, as noted on the original Filing Receipt issued April 22, 2004. Entry of the amendment prior to issue is respectfully requested.

Comments On Statement of Reasons For Allowance

The Notice of Allowance includes an Examiner's Statement of Reasons for Allowance. To the extent that the Examiner's Statement may focus on or highlight specific aspects of the invention as providing a basis for allowance, Applicant responds that it is the invention as a whole that is patentable. That is, the prior art fails to teach or suggest an apparatus as recited in claims 62-66.

In particular, the prior art does not teach or suggest an apparatus for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising (A) a container, (B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump, wherein said container contains (C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises (1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and (2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer, wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and wherein, after application of the system to an area of the dermal surface, the area

becomes touch-dry within three minutes of application, and wherein the physiologically active agent is a hormone for contraception or hormone replacement therapy.

Nor does the prior art teach or suggest an apparatus for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising (A) a container, (B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump, wherein said container contains (C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises (1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and (2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer, wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application, and wherein the physiologically active agent comprises a progestogen other than progesterone.

The prior art also fails to teach or suggest an apparatus for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising (A) a container, (B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump, wherein said container contains (C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises (1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and (2) at least one volatile liquid present in an amount to act as a

vehicle for the active agent and penetration enhancer, wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application, and wherein the physiologically active agent comprises an oestrogen and a progestogen other than progesterone.

Nor does the prior art teach or suggest an apparatus for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising (A) a container, (B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump, wherein said container contains (C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises (1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and (2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer, wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application, and wherein the active agent comprises at least one active agent selected from the group consisting of oestradiol, oestriol, oestrone, ethinyloestradiol, mestranol, stilboestrol, dienoestrol, epioestriol, estropipate, zeranol, progesterone, allyloestrenol, dydrogesterone, lynoestrenol, norgestrel, norethyndrel, norethisterone, norethisterone acetate, gestodene, levenorgestrel, medroxyprogesterone and megestrol.

The prior art also fails to teach or suggest an apparatus for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising (A) a container, (B) a metered dose applicator selected from a metered dose aerosol, a stored energy metered dose pump and a manual metered dose pump, wherein said container contains (C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises (1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt% based on the weight of the active agent or prodrug thereof; and (2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer, wherein the physiologically active agent comprises an oestrogen, and wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and wherein, after application of a metered dose of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application.

CONCLUSION

It is believed that no fees are due. However, in the event that any fees are due, the undersigned authorizes the Commissioner to charge Deposit Account No. 19-0741.

Respectfully submitted,

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By _____

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